An MRI-validated study of Electrical Coupling Index catheter superiority in AF ablation – pre study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28416

Source
Nationaal Trial Register

Brief title
Merci-AF pre study

Health condition

Atrial Fibrillation
DE-MRI
Ablation

Sponsors and support

Primary sponsor: Medisch Spectrum Twente Enschede
Source(s) of monetary or material Support: Initiator = sponsor

Intervention

Outcome measures

Primary outcome

To perform a pre-study to assess the feasibility of DE-MRI to assess lesion size, transmurality and completeness of PVI. The study will be performed to determine if and how DE-MRI can be used in a subsequent multicentre study (MERCI-AF study).

Secondary outcome

To collect data on the use of ECI-feedback which could be included in the MERCI-AF study.

Study description

Background summary

Radiofrequency (RF) pulmonary vein isolation (PVI) represents an established therapy for treating atrial fibrillation (AF). The quality of catheter tip-to-tissue contact plays a critical role in ablation safety and efficacy. Catheters providing feedback on this tip-to-tissue contact have recently become available. Effectiveness of RF ablation by these catheters has recently been demonstrated in humans 1–3. MRI has shown to be of great value in assessing lesion size and transmurality in-vivo. To demonstrate the superiority of using the ECI catheters to conventional catheters for the effectiveness of AF ablation, post procedural MRI with delayed enhancement (DE-MRI) can possibly assess lesion size, transmurality of the lesion and completeness of PVI and relate this to clinical outcome.

Study objective

DE-MRI is feasible to assess lesion size, transmurality and completeness of PVI. The study will be performed to determine if and how DE-MRI can be used in a larger subsequent multicentre trial (MERCI-AF study).

Study design

After 10 patients

Intervention

PVI using electrical coupling information (one side of PV's) or using no celectrical coupling information (other side of PV's)

Contacts

Public
Department of Cardiology

Medisch Spectrum Twente
Haaksbergerstraat 55

J.M. Opstal, van
Enschede 7513 ER
The Netherlands
Scientific
Department of Cardiology
Medisch Spectrum Twente
Haaksbergerstraat 55

J.M. Opstal, van
Enschede 7513 ER
The Netherlands

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Paroxysmal atrial fibrillation for which ≥ 1 electrical and/or chemical cardioversions and persistent atrial fibrillation, eligible for PVI according to current international guidelines.

• Age < 70 years.

• Willing and able to sign informed consent.

• Willing to and capable of following the requested study procedures.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Age < 18 years.

• Pregnancy

• Life or follow-up expectancy < 12 months.

• Previous PVI in history.

• Contrast allergy.

• Creatin clearance level lower than 60.

• MRI scanning not possible (e.g. because of metal implant or claustrophobia).

• Unsuccessful PVI during first procedure, while already in study. This will lead to exclusion after randomisation.

• Abnormal left atrium anatomy defined as number of PV's ≠ 4 . This will lead to exclusion after inclusion but before randomisation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2014
Enrollment:	10
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4116
NTR-old	NTR4357
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A